

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.
43-R-0014

CUSTOMER NO.
1415

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

BOEHRINGER INGELHEIM ANIMAL HEALTH INC
2621 N BELT HWY
ST JOSEPH, MO 64506
(b)(2)High, (b)(7)f

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS(sites)

See Attached Listing

COPY

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs	0	24	0	0	24
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	1,957	1,036	0	2,993
7. Hamsters	0	1,388	2,866	1,656	5,910
8. Rabbits	0	0	1,587	0	1,587
9. Non-Human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

NOV 20 2007 ✓

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer or Legally Responsible Institutional official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE

(b)(6), (b)(7)c

INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

11/13/2007

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

COPY

1. Registration Number: 43-R-0014 / 1415

2. Number 1,656 of animals used in this study.

3. Species (common name) Hamsters of animals used in the study.

4. Explain the procedure producing pain and/or distress.

Box 7E. These animals are used for

(b)(4)

(b)(4)

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency APHIS 9 CFR

(b)(4)

NOV 20 2007

MEMO

COPY

TO: [REDACTED] (b)(6), (b)(7)c listed on APHIS Form 7023
FROM: [REDACTED] (b)(6), (b)(7)c
RE: Explanation of Animals listed in Column E of APHIS Form 7023
Date: November 1, 2007

This memo is required to provide an explanation of the procedures causing pain or distress for the animals listed in column E of APHIS Form 7023 for customer number 1415, registration number 43-R-0014 and to describe why pain and/or distress relief was not provided to the hamsters listed in column E. This memo should accompany the Form 7023.

Hamsters are used for federally mandated testing per [REDACTED] (b)(4)
[REDACTED] (b)(4) pertaining to [REDACTED] (b)(4). This facilities experience with pain relieving drugs in hamsters indicates no observable safety problems. However the experience shows that use invalidates certain aspects of the test. Th [REDACTED] (b)(4)
[REDACTED] (b)(4) in hamsters is somehow altered in treated animals. The number of [REDACTED] (b)(4) expected at a set time is significantly altered. This in turn alters the expected outcomes and invalidates the test. To date no methodology of pain relief is known to be available that will not change the course of the test. It is pointed out however that in other aspects of hamster testing the use of pain relieving drugs has proved successful. These successes are responsible for a 41% reduction from our 2006 experience. It is also noted that the use of pain relieving drugs in guinea pigs has shown continued success to the degree that no animals of this species are listed in column E.

This institution has and will continue to implement 9 CFR section 117.4 (e) which is to intervene, remove and humanely destroy animals if the illness has progressed to a point when death is expected to occur. In addition to the use of drugs to alleviate pain the facility will continue to practice intervention and where possible provide stress reduction by making postural adjustments and to minimally handle affected animals.

These explanations are adequate and complete as I understand the requirement to explain them. I am hopeful the government agencies responsible for animal use and care oversight and for actual animal testing will share useful information on this matter as both industry and government seek reliable non animal testing systems.

[REDACTED]
(b)(6), (b)(7)c

11-1-07

NOV 2 0 2007